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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,449	11/30/2001	Shamim M. Malik	50623.134	3441
7590 12/11/2007 Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111			EXAMINER TYSON, MELANIE RUANO	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/997,449

Applicant(s)

MALIK ET AL.

Examiner

Melanie Tyson

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8-10,13 and 17-31 is/are pending in the application.
- 4a) Of the above claim(s) 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8-10,13, and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to Applicant's amendment received on 24 September 2007.

Claims 17-30 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 2, 4-6, 8-10, 13, and 17-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al. (6,335,029) in view of Ecer et al. (4,486,247).

Kamath discloses an implantable medical device being made from metal or polymer and further discloses that stainless steel is particularly useful as base materials, for vascular stents (col. 4, line 56 to col. 5, line 6). Kamath also discloses the stent being coated with drugs as claimed (see detailed description of Kamath et al. patent).

However, Kamath does not disclose the type of stainless steel materials for making the stent, specifically stainless steel base material containing carbon implanted within the

surface as claimed.

It is well known in the art that stainless steel materials containing carbon implanted within the surface as claimed enhances the strength and hardness of the stainless steel surface. Ecer discloses a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material in order to enhance wear resistance (see detailed description of the Ecer et al. patent). Therefore, it would have obvious to one having ordinary skill in the art at the time the invention was made to use the stainless steel containing carbon implanted within the surface for Kamath et al.'s stent in order to improve wear resistance.

Response to Arguments

4. Applicant's arguments filed 24 September 2007 have been fully considered but they are not persuasive. Applicant argues primarily that there is no motivation to combine the prior art applied. Examiner respectfully disagrees.

Applicant argues that one of ordinary skill would have no reason to modify the Kama device to enhance the wear resistance of the stainless steel as taught by Ecer, since the device of Kamath comprises two layers over the base material, a bioactive layer and a barrier layer, and thus the base material **never** directly contacts the external environment. However, the bioactive layer may be biodegradable or bioabsorbable (for example, see column 6, lines 28-50). The purpose of the barrier layer is to also release drugs, control the release rate of the bioactive layer, and/or to protect the bioactive layer during routine handling until the device reaches the target site (for example, see column 8, lines 7-40). When the layers erode and/or biodegrade, the base material of the

permanent device comes into contact with the external environment and becomes susceptible to wear. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kamath as taught by Ecer.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Thursday 8:30-7 (max flex).

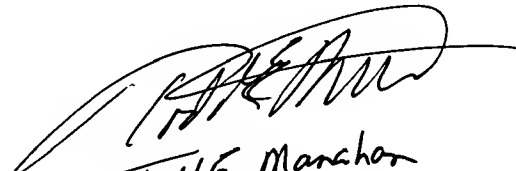
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson *MT*
December 5, 2007


Todd E. Marchon
SPE 3731